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December 8, 1999

Document Management Branch (HFA-305)  
Food and Drug Administration (RE: Docket No. 97N-484S)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Dear Sir/Madam:

I write in opposition of the purposed FDA regulation allowing the FDA to regulate even some types of allograft as medical devices. I am strictly against this. This should be left to mechanical devices, not bone or products procured from humans. Regulations should only pertain to routine disease-free standards, not regulating the device. This would greatly hamper our medical care, as well as obviously increase the cost.

I would be pleased to speak with anyone who wishes. If there are any questions, please contact me. This letter is in reference to Docket No. 97N-484S.

Sincerely,



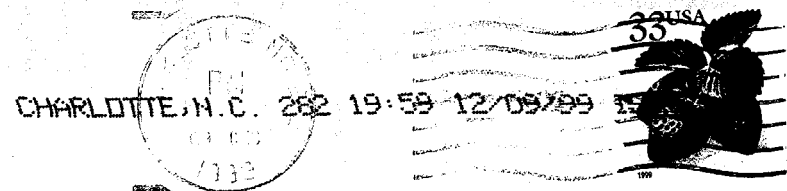
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MAL/pt

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